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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/500,020	Applicant(s) ASHIDA ET AL.	
	Examiner Amy L. Clark	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-16 is/are pending in the application.
- 4a) Of the above claim(s) 4-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgment is made of the receipt and entry of the amendment filed on 17 May 2007 with the amendment of claim 1 and cancellation of claim 17.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

Claims 1 and 3-16 are currently pending.

This application contains claims 4-16 are drawn to an invention nonelected **without** traverse in the reply filed on December 9, 2005. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 1 and 3 are currently under examination.

Response to Arguments

Claim Rejections - 35 USC § 112

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1 and 3 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

This rejection is maintained for reasons of record set forth in the paper mailed on 8 January 2007 and repeated below, slightly altered to take into consideration Applicant's amendment filed on 17 May 2007.

Applicant's arguments have been thoroughly considered, but the rejection remains the same for the reasons set forth in the previous Office action and for the reasons set forth below.

The metes and bounds of Claim 1 are rendered uncertain by the phrase "drying stimulation" in line 12 because it is unclear as to what "drying stimulation" means. What is "drying stimulation"? For example, does Applicant mean that the cells are dried or the cells are exposed to dry compounds? The lack of clarity renders the claims indefinite since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

The claims are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors.

Applicant argues that the Examiner should note that this term ["drying stimulation"] is clarified at page 15, lines 27 - 29 of Applicant's specification. Applicant further argues that drying means complete removal of the supernatant and holding in a CO₂ incubator. Applicant further argues that however, the Examiner should note that this is but one example of drying and is not to be construed as limiting Applicant's invention. Applicant further argues that Applicant has claimed only a drying stimulation and, in accordance with MPEP § 2145 (page 2100-159), arguing limitations which are

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not claimed are not permitted and drying is not limited by the example. Applicant further argues that Applicant only cites this portion of the specification as an example of drying.

However, this is not found persuasive because although the claims are interpreted in light of the specification, it should be noted that limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant further argues that the Examiner's example of exposing the cells to dry compounds will not result in Applicant's invention and exposing the cells to drying compounds will merely create a slurry of the drying compound and the supernatant (liquid above a precipitate, see attached dictionary definition) included with the cells. Applicant further argues that this is similar to mixing a dry powder, such as flour, with water and obtaining a paste and that the paste is not dried.

However, this is not found persuasive because Applicant first of all appears to be presenting an argument with regards to an art rejection, not a rejection under 112 2nd issues. Secondly, while this may be what Applicant is intending the claim, the claims, as written, do not reflect this limitation. Therefore, since Applicant's claims do not reflect this limitations, this rejection still stands based upon how the claims read. Applicant is further directed to the response to Applicant's arguments with regards to the rejection of the claims under 35 U.S.C. 103(a) below.

Applicant further argues that next, the Examiner has objected to the claims as being narrative and indefinite and failing to conform to current US practice and that

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Applicant respectfully traverses this rejection on the grounds that the claims recite specific steps for the claimed screening method. Applicant further argues that the Examiner has not cited any portion of the claim that would support the allegation that the claim is narrative and indefinite. Applicant further argues that absent guidance from the Examiner, Applicant respectfully submits that the claims as submitted are in accordance with US practice and are not merely a literal translation from a foreign document and that the Examiner asserts that the claims are replete with grammatical and idiomatic errors. Applicant further argues that it is respectfully submitted that the Examiner identify what is referred to.

In response to Applicant's arguments, that while it appears that Applicant is intending to claim a screening method, the logic and steps are unclear. For example, lines 8 and 9 of claim 1 are ambiguous, wherein Applicant claims, "selecting test ingredients which reduce the amount of production and/or release of SCF as said active ingredients". Is Applicant claiming that the test ingredients are active ingredients or is Applicant claiming that the production and/or release of SCF is the active ingredient. The Examiner believes that Applicant should amend the claims to be less ambiguous. The Examiner is only providing minor corrections but it is up to Applicant to amend the claims in such a way that the claims are less ambiguous. An example of some corrections to help clarify claim 1 are as follows:

A screening method for active ingredients which exhibit effects of ameliorating pruritus, rough skin or sensitive skin, or effects of skin whitening, by inhibiting production and/or release of stem cell factor (hereinafter, SCF), wherein the method

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~~being characterized by comprising~~ comprises the steps of: contacting epidermal keratinocytes with test ingredients, assaying the amount of SCF produced and/or released by said cells, and selecting test ingredients which reduce the amount of production and/or release of SCF as said active ingredients, wherein said epidermal keratinocytes are subjected to stimulation to promote SCF production and/or release, and wherein said stimulation is drying stimulation.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1 and 3 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Mak (A*, US Patent Number 6,190,691 B1), in view of Bissonnette et al. (U*, J Allergy Clin Immunology, 1997; 100 (6, Pt. 1): 825-831) and Denda (V*, J. Dermatol. Sci. 2000; 24 Suppl 1: S22-S28).

This rejection is maintained for reasons of record set forth in the paper mailed on 8 January 2007 and repeated below, slightly altered to take into consideration Applicant's amendment filed on 17 May 2007.

Applicant's arguments have been thoroughly considered, but the rejection remains the same for the reasons set forth in the previous Office action and for the reasons set forth below.

Mak teaches a number of screening methods for evaluating compounds capable of suppressing cytokine production either *in vitro* or *in vivo* (See abstract). Mak further

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teaches a method of screening for skin immune or inflammation modulating agents, wherein keratinocytes are stimulated to produce at least one cytokine or MHC Class II molecule and that a portion of the keratinocytes are exposed to a putative skin inflammation modulating agent and a determination is made as to whether the putative agent is effective to modulate the production of the cytokine or MHC class II molecule in the exposed keratinocytes (See column 3, lines 13-21). Mak further teaches a method of treating a pathological condition mediated by TNF production in a mammal by administering a therapeutically effective amount of a potassium sparing diuretic, antidiarrheal, cyclic AMP modulating agent or calcium channel blocker (See column 3, lines 30-48), wherein the pathological condition is a skin inflammatory condition such as psoriasis, atopic dermatitis, UV-induced inflammation, contact dermatitis or inflammation induced by other drugs (See column 3, lines 59-64). Mak further teaches that normal or healthy skin contains no signs of mast cell degranulation (See column 6, lines 51-65) and that TNF inhibitors or TNF antagonist refer to agents which reduce the production of TNF in any TNF producing cell, including keratinocytes and mast cells (See column 7, lines 27-31). Mak further teaches that the skin makes TNF and that there is a strong link between pathogenesis of psoriasis and the localized production of TNF (See column 10, lines 37, 38 and 53-67 continued into column 11, lines 1-7). Mak further teaches that the method derives from a sequence of cellular events which lead to the skin inflammatory response, wherein the sequence includes the phases of loss of accentuated transepidermal water loss cause by an insult, injury or other chemical or physical stimulus to the skin, consequent change in the ion gradients normally

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maintained in the skin, the release of pre-formed cytokines, resulting in full-blown inflammation and the transduction of signals by keratinocytes to produce and/or secrete additional cytokines, wherein the method exploits these sequences of events to provide superior screening methods for anti-inflammatory drugs as well as superior anti-inflammatory agents, methods and compositions (See column 12, lines 48-62). Mak further teaches methods for treating pathological conditions mediated by TNF production in a mammal using pharmacological agents to regulate the formation, release and biological reactions of TNF and other proinflammatory cytokines or other immunomodulatory substances, such as calcium channel blockers, diuretics, antidiarrheals, phosphodiesterase inhibitors and .beta.-agonists and that within each of these groups are representative members which inhibit TNF production and which are now identified as TNF inhibitors by the screening methods described herein and that the methods of treatment provided by the present invention use those calcium channel blockers, diuretics, antidiarrheals, phosphodiesterase inhibitors and .beta.-agonists which also inhibit TNF production (See column 29, lines 64-67 and column 30, lines 1-14).

Bissonnette teaches a method to determine that beta 2-agonist inhibit the release of preformed mediators, such as histamine, from mast cells and that beta 2-agonists demonstrate anti-inflammatory activity by inhibiting the release of TNF-alpha from mast cells stimulated through their IgE receptor or by a tumor target cell. Please note that stem cell factor (SCF) binds to c-Kit and is an important mediator of survival, growth, and function of cells mast cells and, therefore, stem cell factor plays an important role in

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mast cell proliferation and development. Furthermore, SCF modulates the release by mast cells of preformed (histamine) and newly generated (TNF-alpha) mediators.

Denda teaches that a dry environment contributes to the exacerbation of cutaneous disorders such as epidermal hyperplasia, mast cell degranulation and cytokine secretion.

The teachings of Mak, Bissonnette and Denda are set forth above. Mak does not expressly teach a method comprising the steps of assaying the amount of SCF produced and/or released by keratinocytes and selecting test ingredients which reduce the amount of production and/or release of SCF as said active ingredients, wherein said epidermal keratinocytes are subjected to stimulation to provide SCF production and/or release. However, at the time the invention was made, it would have been obvious to one of ordinary skill in the art and one would have been motivated and had a reasonable expectation of success to modify the method taught by Mak by assaying the amount of SCF produced and/or released by keratinocytes and selecting test ingredients which reduce the amount of production and/or release of SCF as said active ingredients, wherein said epidermal keratinocytes are subjected to stimulation to provide SCF production and/or release because at the time the invention was made, a number of screening methods for evaluating compounds capable of suppressing cytokine production either *in vitro* or *in vivo*, as was a method of screening for skin immune or inflammation modulating agents, wherein keratinocytes are stimulated to produce at least one cytokine or MHC Class II molecule and that a portion of the keratinocytes are exposed to a putative skin inflammation modulating agent and a

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determination is made as to whether the putative agent is effective to modulate the production of the cytokine or MHC class II molecule in the exposed keratinocytes, as was a method of treating a pathological condition mediated by TNF production in a mammal by administering a therapeutically effective amount of a potassium sparing diuretic, antidiarrheal, cyclic AMP modulating agent or calcium channel blocker, wherein the pathological condition is a skin inflammatory condition such as psoriasis, atopic dermatitis, UV-induced inflammation, contact dermatitis or inflammation induced by other drugs, as was a method derived from a sequence of cellular events which lead to the skin inflammatory response, wherein the sequence includes the phases of loss of accentuated transepidermal water loss cause by an insult, injury or other chemical or physical stimulus to the skin, consequent change in the ion gradients normally maintained in the skin, the release of pre-formed cytokines, resulting in full-blown inflammation and the transduction of signals by keratinocytes to produce and/or secrete additional cytokines, wherein the method exploits these sequences of events to provide superior screening methods for anti-inflammatory drugs as well as superior anti-inflammatory agents, methods and composition, methods for treating pathological conditions mediated by TNF production in a mammal using pharmacological agents to regulate the formation, release and biological reactions of TNF and other proinflammatory cytokines or other immunomodulatory substances, such as calcium channel blockers, diuretics, antidiarrheals, phosphodiesterase inhibitors and .beta.-agonists and that within each of these groups are representative members which inhibit TNF production and which are now identified as TNF inhibitors by the screening

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methods described herein and that the methods of treatment provided by the present invention use those calcium channel blockers, diuretics, antidiarrheals, phosphodiesterase inhibitors and .beta.-agonists which also inhibit TNF production, that normal or healthy skin contains no signs of mast cell degranulation and that TNF inhibitors or TNF antagonist refer to agents which reduce the production of TNF in any TNF producing cell, including keratinocytes and mast cells, that the skin makes TNF and that there is a strong link between pathogenesis of psoriasis and the localized production of TNF were known at the time the invention was made, as clearly taught by Mak, as was a method to determine that beta 2-agonist inhibit the release of preformed mediators, such as histamine, from mast cells and that beta 2-agonists demonstrate anti-inflammatory activity by inhibiting the release of TNF-alpha from mast cells stimulated through their IgE receptor or by a tumor target cell, as clearly taught by Bissonette, as was that a dry environment contributes to the exacerbation of cutaneous disorders such as epidermal hyperplasia, mast cell degranulation and cytokine secretion, as clearly taught by Denda. Therefore, it would have been obvious to one of ordinary skill in the art, one would have been motivated and had a reasonable expectation of success to modify the method taught by Mak because at the time the invention was made it would have been well within the purview of one of ordinary skill in the art to measure the amount of stem cell factor released upon exposing keratinocytes with test ingredients upon stimulating keratinocytes with either drying or chemical stimulation and selecting test ingredients which reduce the amount of stem cell factor production and/or released by said cells and selecting test ingredients which reduce the

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amount of production and/or release of stem cell factor as said active ingredients because dry conditions promote mast cell degranulation, as clearly taught by Denda, as do chemicals such as RETIN-A (all trans retinoic acid), as clearly taught by Mak (See column 3, line 64).

Moreover, it would have been merely a matter of judicious selection to one of ordinary skill in the art at the time the invention was made to modify the referenced method because it would have been well in the purview of one of ordinary skill in the art practicing the invention to pick and choose a ingredients to inhibit the amount of production and/or release of stem cell factor by contacting epidermal keratinocytes with test ingredients and assaying the amount of stem cell factor released, as clearly taught by Mak, Bissonette and Denda.

Based upon the beneficial teachings of the cited references, the skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Applicant argues that the Examiner recognizing that the combination of references do not teach steps of assaying SCF then begins an argument on the bottom of six and continuing through line 4 of page 9, by discussing features of certain of the references. Applicant further argues that the Examiner never explains why one of ordinary skill in the art would find a suggestion or reason to combine the references in

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the manner claimed in the references and that the Examiner asserts that one would have been motivated and had a reasonable expectation of success to modify Mak because it would be in the purview of one of ordinary skill in the art to measure the amount of stem cell factor. However, the Examiner never explains why the references would suggest stem cell factor or basis for the purview. Applicant further argues that at the bottom of page 9, the Examiner, beginning at line 5 up from the bottom states that it would be in the purview in one of ordinary skill in the art of practicing the invention to pick and choose ingredients to inhibit the amount or production or release stem cell factor and that this is hindsight use of Applicant's specification and claims. Applicant further argues that only Applicant teaches the invention, not the art and such hindsight is impermissible.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Applicant further argues that still further, the Examiner asserts that it would be obvious to pick and choose and that this is also an impermissible rejection because it only boils down to a rejection which is "it is obvious to try" and that obvious to try

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rejections are not supported by facts that teach or suggest an invention and that the Examiner has totally over looked the fact that the essence of the present invention (stem cell factor) is based upon the discovery that SCF production or its release can be promoted by drying of epidermal keratinocytes, and that as a result, screening for active ingredients which inhibit production and/or release of SCF can be carried out easily.

Applicant further argues that the Examiner has made no reference to anything in the art that would teach or suggest this at all. Applicant further argues that still further, the Examiner has referred to Applicant's description at page 3, lines 21 to 26 and Applicant's experimental example 1, pages 15 to 16 of Applicant's specification and in the specification at page 3, it is stated that the inventors have discovered that SCF production and/or release can be promoted by stimulation and in Applicant's claim 1, this stimulation is a drying stimulation and that the drying is of human epidermal keratinocytes and that this result is disclosed as being successful in efficiently screening for active ingredients that can effectively inhibit production and/or release of SCF.

Applicant further argues that Applicant's specification cannot be used against Applicant in this manner. Applicant further argues that in Example 1, found at pages 15 and 16, Applicant outlines the use of drying stimulation and its relation to SCF production and that the Examiner has shown nothing in the prior art that would link a drying simulation to SCF production in the references when combined. Applicant further argues that in the other hand, claim 1 clearly provides the necessary connection between the drying stimulation and the SCF production as stated and that finally, the combination of references as admitted by the Examiner lacks SCF and that SCF is in no reference.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the Examiner has provided adequate reasons for how these reference may be combined. Furthermore, KSR forecloses the argument that a **specific** teaching, suggestion, or motivation is required to support a finding of obviousness. See the recent Board decision *Ex parte Smith*, --USPQ2d--, slip op. at 20, (Bd. Pat. App. & Interf. June 25, 2007)(citing *KSP*, 82 USPQ2d at 1396)(available at <http://www.uspto.gov/web/offices/dcom/bpai/prec/fd071925.pdf>).

In response to applicant's argument that the Examiner has shown nothing in the prior art that would link a drying simulation to SCF production in the references when combined. Applicant further argues that in the other hand, claim 1 clearly provides the necessary connection between the drying stimulation and the SCF production as stated and that finally, the combination of references as admitted by the Examiner lacks SCF and that SCF is in no reference, the Examiner was not admitting that there was no mention of SCF, but rather that the Examiner was explaining what was lacking in the reference. Please note that stem cell factor (SCF) binds to c-Kit and is an important mediator of survival, growth, and function of cells mast cells and, therefore, stem cell

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factor plays an important role in mast cell proliferation and development. Furthermore, SCF modulates the release by mast cells of preformed (histamine) and newly generated (TNF-alpha) mediators. Therefore, there is a direct correlation between stem cell factors and mast cells and that stem cell factors are responsible for regulating mast cells.

No claims are allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy L. Clark whose telephone number is (571) 272-1310. The examiner can normally be reached on 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Amy L. Clark
AU 1655

Amy L. Clark
August 5, 2007


MICHELE FLOOD
PRIMARY EXAMINER